Designation: F136 – 13 (Reapproved 2021)ε1

Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)[1]

This standard is issued under the fixed designation F136; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—X2.2 was updated editorially in August 2021.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy (R56401) to be used in the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E290 Test Methods for Bend Testing of Material for Ductility

E539 Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry

E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion

E1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone

2.2 *ISO Standards:*[3]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems Requirements

2.3 *ASQ Standard:*[4]

ASQ C1 Specifications of General Requirements for a Quality Control Program

2.4 *Aerospace Material Specifications:*[5]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2631 Ultrasonic Inspection—Titanium and Titanium Alloy Bar and Billet

AMS 2380 Approval and Control of Premium Quality Titanium Alloys

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *beta transus, n*—the minimum temperature at which the alpha plus beta phase can transform to 100 % beta phase.

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[5] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

3.1.2 *lot, n*—the total number of mill products produced from one heat under the same conditions at essentially the same time.

4. Product Classification

4.1 *Strip*—Any product under 0.1875 in. (4.76 mm) in thickness and under 24 in. (610 mm) wide.

4.2 *Sheet*—Any product under 0.1875 in. (4.76 mm) in thickness and 24 in. (610 mm) or more in width.

4.3 *Plate*—Any product 0.1875 in. (4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4.00 in. (101.60 mm), thick inclusive is covered by this specification.

4.4 *Bar*—Round bars and flats from 0.1875 in. (4.76 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other sizes and shapes by special order).

4.5 *Forging Bar*—Bar as described in 4.4, used for production of forgings, may be furnished in the hot worked condition.

4.6 *Wire*—Rounds, flats, or other shapes less than 0.1875 in. (4.76 mm) in diameter.

4.7 *Other*—Other forms and shapes, including tubing, may be provided by agreement between purchaser and supplier.

5. Ordering Information

5.1 Include with inquiries and orders for material under this specification the following information:

5.1.1 Quantity,

5.1.2 ASTM designation and date of issue,

5.1.3 Form (sheet, strip, plate, bar, forging bar, or wire),

5.1.4 Condition (see Section 3 and 6.3),

5.1.5 Mechanical properties (if applicable, for special conditions),

5.1.6 Finish (see 6.2),

5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,

5.1.8 Special tests, if any, and

5.1.9 Other requirements.

6. Materials and Manufacture

6.1 The various titanium mill products covered in this specification normally are formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

6.2 *Finish*—The mill product may be furnished to the implant manufacturer as mechanically descaled or pickled, abrasively blasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by grinding if the resultant area meets the dimensional and surface finish requirements of this specification.

6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition. Mechanical properties for conditions other than those listed in Tables 1 and 2 may be established by agreement between the supplier and the purchaser.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition specified in Table 3. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product. The supplier shall not ship material with chemistry outside the requirements specified in Table 3.

7.1.1 Requirements for the major and minor elemental constituents are listed in Table 3. Also listed are important residual elements. Analysis for elements not listed in Table 3 is not required to verify compliance with this specification.

7.2 *Product Analysis:*

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The product analysis tolerances shall conform to the product tolerances in Table 4.

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or determining variations in the composition within the heat.

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis. Product analysis outside the tolerance limits allowed in Table 4 is cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

TABLE 1 Annealed Mechanical Properties of Bar, Wire, and Forgings

Nominal Diameter or Distance Between Parallel Sides, in. (mm)	Tensile Strength min, psi (MPa)	Yield Strength (0.2 % offset) min, psi (MPa)	Elongation[A] in 4D or 4W min, %			Reduction of Area[B] min, %		
			L	LT	ST	L	LT	ST
			—	—	—	—	—	—
Under 0.187 (4.75) thickness or diameter	125 000 (860)	115 000 (795)	10	...	...	...	...	...
0.187 (4.75) to under 1.75 (44.45), incl	125 000 (860)	115 000 (795)	10	...	...	25	...	...
1.75 (44.45) to under 2.50 (63.50), incl	120 000 (825)	110 000 (760)	8	...	...	20	...	...
2.50 (63.50) to 4.00 (101.60), incl	120 000 (825)	110 000 (760)	8	8[C]	8[C]	15	15[C]	15[C]

[A] Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4 D or 4 W. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross-sectional area.) Gage length shall be reported with the elongation value. L = longitudinal; LT = long transverse; ST = short transverse.

[B] Applies to bar and forgings only. L = longitudinal; LT = long transverse; ST = short transverse. For round bar, the long and short transverse are identical tests, therefore only one transverse is required.

[C] Transverse requirements in Table 1 apply only to product from which a tensile specimen not less that 2.50 in. (63.5 mm) in length can be obtained.